

Applicants' research has failed to uncover any claim that makes Tuohy-Borst a trademark and it has never been registered - tuohy-borst - has become a generic description for a type of fitting used with catheters. If the Examiner can identify a trademark registration number - Applicants will reconsider.

Claims Rejections 35 U.S.C. § 112, Second Paragraph

Claims 1-14 were rejected based their preamble. The preambles of Claims 1-14 have been amended.

Claim 12 was rejected as claim elements lacked antecedent basis. The claim has been amended.

Claims Rejection - Section 102(b)

Claims 1, 6, 8-12, and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Braunschweiler et al. (U.S. PN 5,484,444).

Examiner writes that the outer body proximal end tubular body handle 5 and elongated core element handle 6, (Col. 3, li. 64 to Col. 4 , li 2), are "handles with moveable knobs connected to both shafts for manipulating reciprocal motion (5,6), . . . ." Applicants' traverse.

There is no mention in the '444 patent of movable knobs coupled to both shafts. The '444 patent discusses relative motion between the core element 3 and the outer body 2, but provides no description whatsoever about how such relative motion would be accomplished.

Claim 1 recites

e) means coupled to the inner shaft and outer shaft for manipulating the outer shaft with respect to the inner shaft; and

The '444 patent does not disclose <sup>Not claimed this way</sup> a single means coupled to both the inner and outer shaft. The '444 patent discloses two handles (5,6) each connected separately to its member, not one handle coupled to both as required by Claim 1. The '444 patent does not disclose element coupled to both and as such fails to anticipate Claim 1.

Claims 6, 8-12, and 14 are Claims dependent on Claim 1 and are not anticipated for at least the same reasons as Claim 1, as discussed above. Further, the '444 patent contains no reference to a "handle and knob" coupled combination as recited in the Claims of the present application. Further while the '444 patent discloses an endoprosthesis with "individual threads of a layer of endoprosthesis 1" (Col. 4, li. 42-43). It does not disclose an endoprosthesis having segments as

I  
means  
are handles  
(5,6)

? II  
See  
Claim 8  
are handles  
is a knob?

recited in Claim 14, "wherein the stent has a plurality of segments in a first radial position and a plurality of second segments in a second radial position when in an unexpanded configuration." The segments referred to in Claim 14, are (temporarily) pushed in and do not form a second layer as in the '444 patent. The layers of the endoluminal prosthesis in the '444 do not promote the reduction of the prosthesis to a smaller diameter for delivery. Multiple layers do not make a plurality of segments. Therefore anticipation does not apply.

*III disagree*

Claims Rejection - Section 103(a)

Claims 2-5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Braunschweiler et al. (5,484,444) in view of Lenker et al. (5,683,451).

The discussion above, discusses the absence of support for a rejection based on the '444 patent. The unsuggested combination with Lenker '451, does not present a sustainable rejection.

*III disagree*

Lenker discloses channels "in" the catheter cover or shaft. Lenker fails to disclose a channel member "between" the inner shaft <sup>yes he does</sup> and the outer shaft. As shown in Figure 5 of the present application the inner shaft 24 is a different structure from the outer shaft 26, and still a separate structure is channel spacer (member) 62. There is no structure <sup>doesn't have to be</sup> separate from the inner and outer shaft to be identified as a channel member in Lenker'451. An intermediary structure is simply not disclosed. Nor is there any suggestion to combine Lenker '451 with the '444 patent and therefore the requirement for a rejection on the basis of obviousness have not been met.

Claims Rejection - Section 103(a)

Claim 7 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Braunschweiler et al. (5,484,444) in view of Williams et al. (5,391,172).

The discussion above, discusses the absence of support for a rejection based on the '444 patent. The unsuggested combination with Williams '172, does not present a sustainable rejection.

*IV ?*

Unlike the valve relief which is conspicuously absent from the disclosure in Williams '172. There is no correlation with the "flush port" 250 described in Williams '172. In the present application a "[v]alve relief 58 allows the practitioner to close the hemostatic valve or tuohy-borst coupler about valve relief 58, reducing back bleed while permitting free movement of the delivery system 10 during the procedure." This is nothing like the function described in the Williams '172 patent. Nor is there any suggestion to combine Williams '172 with the '444 patent and therefore the requirement for a rejection on the basis of obviousness have not been met.

Claims Rejection - Section 103(a)

Claim 13 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Braunschweiler et al. (5,484,444) in view of Lange et al. (6,036,682).

The discussion above, discusses the absence of support for a rejection based on the '444 patent. The unsuggested combination with Lange '682, does not present a sustainable rejection.

Unlike the integral and catheter surface mounted markers disclosed in Lange '682. In the current disclosure "[a] radiopaque marker 40 is located on outer shaft distal end. Radiopaque marker 40 enables the practitioner to view the outer shaft 26 position during the procedure." The marker on an outer sleeve which is then retracted over a self expanding stent for deployment allows the user to view the progress of the procedure. This is nothing like this function described in the Lange '682 patent. Nor is there any suggestion to combine Lange '682 with the '444 patent and therefore the requirement for a rejection on the basis of obviousness have not been met.

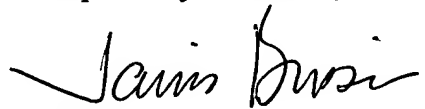
II

**CONCLUSION**

Applicant believes that claims are patentable for the reasons set forth above, and that the application is now in a condition for allowance. Accordingly, an notice of allowance is respectfully requested.

Dated this 13th day of May, 2002.

Respectfully Submitted,



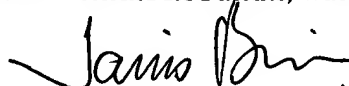
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**CERTIFICATE OF MAILING (37 CFR 1.8A)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in the envelope addressed to: Box Fee Amendments, Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: July 8, 2002

  
Janis Biksa

AMENDED CLAIMS MARKED UP

1. (Amended) A [device for delivering a stent, the device] stent delivery system, the system comprising:
  - a) an inner shaft having a proximal end and a distal end;
  - b) an outer shaft moveable with respect to the inner shaft, the outer shaft having a proximal end and a distal end;
  - c) a stent receiving area on the inner shaft adjacent the inner shaft distal end;
  - d) a tapered tip mounted on the inner shaft distal end;
  - e) means coupled to the inner shaft and outer shaft for manipulating the outer shaft with respect to the inner shaft; and
  - f) a stent positioned in the stent receiving area..
2. (Amended) The stent delivery system [A device] of claim 1 and further comprising a channel member disposed between the inner shaft and the outer shaft.
3. (Amended) The stent delivery system [A device] of claim 2 wherein the channel member defines a plurality of channels extending along a length of a lumen defined between the outer shaft and the inner shaft.
4. (Amended) The stent delivery system [A device] of claim 3 wherein the channel member defines eight channels extending along the length of the lumen defined between the outer shaft and the inner shaft.
5. (Amended) The stent delivery system [A device] of claim 2 wherein the channel member extends from the inner shaft.
6. (Amended) The stent delivery system [A device] of claim 1 and further comprising a radiopaque marker on the inner shaft approximate the stent receiving area.
7. (Amended) The stent delivery system [A device] of claim 1 and further comprising a coupling member on said outer shaft and a valve relief, the coupling member selectively coupling the valve relief to the outer shaft.
8. (Amended) The stent delivery system [A device] of claim 1 wherein the means coupled to the outer shaft and inner shaft comprises a handle with a reciprocating knob coupled to the outer shaft whereby the outer shaft is moved with respect to the movement of the knob.
9. (Amended) The stent delivery system [A device] of claim 1 wherein the means coupled to the outer shaft and inner shaft includes a moveable knob coupled to the inner shaft for moving the inner shaft longitudinally with respect to the outer shaft.
10. (Amended) The stent delivery system [A device] of claim 1 wherein the tip has a proximal end and a distal end and the tip is tapered towards its distal end.
11. (Amended) The stent delivery system [A device] of claim 1 wherein the stent

receiving area has a stent stop.

12. (Amended) The stent delivery system [A device] of claim 1 wherein [the] a stent stop comprises [the] a radiopaque marker.

13. (Amended) The stent delivery system [A device] of claim 1 and further comprising a radiopaque marker on the distal end of the outer shaft.

14. (Amended) The stent delivery system [A device] of claim 1 wherein the stent has a plurality of segments in a first radial position and a plurality of second segments in a second radial position when in an unexpanded configuration.